

Alexander S. Mathews  
President & CEO

2360 '99 JUL 19 P2:04  
July 9, 1999

Stephen F. Sundlof, DVM, PhD  
Director (HFV-1)  
Center for Veterinary Medicine  
Food and Drug Administration  
7500 Standish Place  
Rockville, Maryland 20855

Re: Citizen Petition 98P-1123/CP

Dear Dr. Sundlof:

This acknowledges your letter of June 10, 1999, providing "an interim response" to the Animal Health Institute (AHI) Citizen Petition identified above, requesting that the Food and Drug Administration (FDA) immediately suspend requests of sponsors of antibacterial animal drugs to commit to certain post-approval conditions. For the reasons set out below, AHI intends to treat your letter as a constructive denial of our Petition, and to proceed accordingly.

Our Petition, like your letter, acknowledged the complexity of the issues involved in evaluating the human food safety of the use of antibacterial drugs in food producing animals. For that reason, and the lack of scientific or regulatory consensus with respect to the resolution of these issues, we believe it is premature for CVM to adopt regulatory requirements in the approval process of new animal drugs that in effect assume a particular resolution of these very issues. Our Petition requested that CVM cease the implementation of these novel regulatory requirements until the underlying scientific and regulatory issues had been resolved through appropriate notice and comment rulemaking. As your letter acknowledges, the process of resolving these issues requires a "careful and thorough scientific, legal, and policy consultation, analysis and coordination within the agency."

But CVM continues to request that sponsors initiate actions that would be appropriate only if the Framework were unchanged, something that CVM cannot assume at this point. Rather than acting on our Petition, CVM is postponing a response until after it has a final Framework. That action represents the constructive denial of the Petition, as it would be moot at that point. AHI intends to proceed on the basis of this constructive denial.

Sincerely yours,



Alexander S. Mathews

98P-1123

LET 2